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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,647	04/04/2001	Ginette Serrero	A7542.0000/P001-E	2662
7.	590 10/01/2002			
James W. Brady, Jr. DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP 2101 L. Street NW			EXAMINER	
			DAVIS, NATALIE A	
Washington, DC 20037-1526		ART UNIT	PAPER NUMBER	
			1642	()
			DATE MAILED: 10/01/2002	$\mathcal{D}$

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
· ·	09/824,647	SERRERO, GINETTE			
Offic Action Summary	Examiner	Art Unit			
•	Natalie A. Davis	1642			
The MAILING DATE of this communication app					
Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be ting within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed  s will be considered timely. the mailing date of this communication. (I) (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on <u>04 A</u>					
, <u> </u>	is action is non-final.	recognition as to the morits is			
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. <b>Disposition of Claims</b>					
4)⊠ Claim(s) <u>1-5,14-16,19 and 24-26</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>1-5,14-16,19 and 24-26</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or	r election requirement.				
Application Papers					
9) ☐ The specification is objected to by the Examiner.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.					
If approved, corrected drawings are required in reply to this Office action.  12) The oath or declaration is objected to by the Examiner.					
Priority under 35 U.S.C. §§ 119 and 120					
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) ☐ All b) ☐ Some * c) ☐ None of:	·	, (4) 6. (-).			
1. Certified copies of the priority documents	s have been received.				
2. Certified copies of the priority documents		ion No.			
Copies of the certified copies of the prior application from the International Bur     See the attached detailed Office action for a list of the certified copies of the prior application.	ity documents have been receive reau (PCT Rule 17.2(a)).	ed in this National Stage			
	·				
<ul> <li>14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).</li> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> </ul>					
15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.					
Attachment(s)	_				
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5	5) Notice of Informal I	y (PTO-413) Paper No(s) Patent Application (PTO-152)			

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#### **DETAILED ACTION**

Applicant's preliminary amendment filed 4 April 2002 (Paper No: 7) is acknowledged. Accordingly, claims 1, 15, and 24 are amended, claims 6-13, 17, 18, 20-23, and 27 are cancelled, claims 1-5, 14-16, 19, and 24-26 are pending and under examination.

### Information Disclosure Statement

The information disclosure statement filed 22 November 2001 has been considered. A signed copy is attached hereto.

# Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 2. Claims 1-5, 14-16, 19, and 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 14, and 25-26 recites the limitation "agent". There is insufficient antecedent basis for this limitation in the claim.

# Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 4. Claim1-5, 14-16, 19, and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Shoyab, et al, (1991, WO 91/15510).

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Shoyab teach a novel family of growth regulatory proteins called epithelins (GP88), which are capable of stimulating and inhibiting cell growth and may be used in the diagnosis and treatment of disease (p. 1). Shoyab further teach anti-sense epithelin molecules for therapeutic purposes via the inhibition of translation of epithelin-encoding mRNA. In addition, Shoyab teach that epithelin 1 antisense RNA could be useful as an epithelin antagonizing agent in the treatment of diseases caused by epithelin 1 (p. 31), the use of antibodies capable of neutralizing epithelin 1 stimulatory activity in the inhibition of epithelin 1 activity, claim a method of treatment by inhibiting epithelin growth stimulatory activity, and the production of anti-epithelin antibodies using epithlin peptides (p. 18). Shoyab is silent as to whether the antisense epithelin hybridizes to the claimed sequences and what amino acid regions the epithelin antibody was made against. However, it is inherent that the antisense epithelin is capable of hybridizing to at least a portion of the claimed nucleotide sequence, since Shoyab teach anti-sense epithelin as an inhibitor of translation and the antibody was made against the amino acid sequences as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, PhD September 30, 2002

> MUCA JUM SHEELA HUFF RIMARY EXAMINER